CASE REPORT FORM SAMPLE

NCI, DCP, Chemoprevention Branch Sponsored Clinical Trials

Protocol Number

Phase II Clinical Trial of XXXXXX

Patient ID: _____

Principal Investigator: _____

Site: _____

INSTRUCTIONS FOR COMPLETING THE FORMS

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INSTRUCTIONS FOR COMPLETING THE FORMS

Complete the appropriate forms at time points where an "X" is marked:

Form	Screen	Baseline	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9
On Study	X										
Eligibility Checklist[1]	X										
Medical History	X										
Surgical History	X										
Physical Examination[2]	X	X	X	X	X	X	X	X	X	X	X
Laboratory Data[3]	X		X	X	X	X	X	X	X	X	X
Study Drug Administration			X	X	X	X	X				
Concomitant Drug		X	X	X	X	X	X				
Drug Calendar Record			X	X	X	X	X				
ADR			X	X	X	X	X	X	X	X	X
Agent Specific ADR			X	X	X	X	X	X	X	X	X
Social Habits Changes			X	X	X	X	X	X	X	X	X
Efficacy: SEBs Data	X					X	X		X		

INSTRUCTIONS FOR COMPLETING THE FORMS

Form	Screen	Baseline	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9
Physician's Notes[4]	o o o o									o o o o	
Off Study								X			
Follow-up								X	X	X	X
Questionnaires											
Dietary	X										
Smoking	X										
Alcohol	X										

[1] Includes Informed Consent.
[2] Includes eye examination, oral biopsies and scrapings, and photographs.
[3] Includes pregnancy test, chest and spine X-rays.
[4] The Physician's Notes Form is used as necessary.

Protocol Number (Title)
Patient ID: _____ Patient DOB: _____

ON STUDY FORM

Date of Birth: ___/___/___
mo day yr

Weight: ___ lbs
Height: ___ ft ___inches

Race: (circle one) Caucasian Black Oriental Hispanic Other: _____

Gender: (circle one) Female Male

Histology (dysplastic leukoplakia > 1 cm diameter): (circle one) YES NO

Date Diagnosed: ___/___/___
mo day yr

Date Screened: ___/___/___
mo day yr

Date Enrolled: ___/___/___
mo day yr

Date Randomized: ___/___/___
mo day yr

Date Run-in Began: ___/___/___
mo day yr

Date Treatment Began: ___/___/___
mo day yr

Site: _____

Physician: _____, M.D.

PI:_____
Data Entry: _____
Monitor: _____

Protocol Number (Title)
Patient ID: _____ Patient DOB: _____

ELIGIBILITY CHECKLIST

Please circle YES or NO; Answers to questions 1-8 must be YES to be ELIGIBLE[1]:

1. Informed Consent Signed (date:_____)	YES	NO
2. Over 18 years of age	YES	NO
3. Performance status of ECOG 0-2	YES	NO
4. Acceptable hematopoietic, hepatic, and renal function (WBC >= 3500 µL, platelet count >= 100,000/µL, serum creatinine < 1.6 mg/dl, serum bilirubin <= 1.6 mg/dl, transaminases < twice normal limits)	YES	NO
5. Compliance acceptable *(after run-in)* (80%)	YES	NO
6. Negative pregnancy test and will use contraceptives	YES	NO

Please circle YES or NO; Answers to questions 9-17 must be NO to be ELIGIBLE:

7. Abnormal organ function	YES	NO
8. Fasting cholesterol or triglycerides > 300 mg/dl	YES	NO
9. Severe heart disease (Class III-IV, NY Heart Assoc.)	YES	NO
10. Recent (within 3 months), chronic high dose vitamin A use (> 30,000 IU/day)	YES	NO
11. Uncontrolled medical disease or history of seizure	YES	NO

[1] The Registrant is responsible for the accuracy of information. Detailed Eligibility Checklist is found within the protocol.

Registrant Name: _____ Signature:_____
Date: ___/___/___

PI:_____
Data Entry: _____
Monitor: _____

MEDICAL HISTORY

Please Check one YES or NO; provide details if checked YES. Use Physician's Notes Form if need more space and note in the Description of Condition Column.

Date Medical History Taken: __/__/__

Condition	NO	YES	Description of Condition
Cancer			
Family Cancer			
Cardiovascular Disease			
Bronchopulmonary Disease			
Hepatobiliary Disease			
Gastrointestinal Disease			
Genitourinary Disease			

MEDICAL HISTORY

Condition	NO	YES	Description of Condition
Endocrine/Metabolic Disease			
Diabetes: (circle one) Insulin-dependent Non-insulin dependent			
Hematological Disease			
Dermatological Disease			
Musculoskeletal Disease			
Neurological Disease			
Seizures			
Psychological Disease			

MEDICAL HISTORY

Condition	NO	YES	Description of Condition
Immunological Disease			
Infectious Disease, specify if HIV positive			
Allergy			
Alcohol Use (frequency/day for how long)			
Smoking (No. smoked/day, how many years, or stopped)			
Use of other drugs; if YES describe PRESCRIPTION DRUGS on CONCOMITANT DRUG FORM)			
Trauma (past 6 months), if YES, specify date(s)			
Other, specify			

SURGICAL HISTORY

Please provide the surgery history; if NONE, please circle below. Use Physician's Notes Form if need more space and note in the Previous Surgery Column.

Date Surgical History Taken: __/__/__

No previous surgery was performed: NONE

Previous Surgery (Describe)	NO	YES	Date mo/day/yr

PHYSICAL EXAMINATION

Please use Physician's Notes Form, if more space is required.

General Examination (Part 1)

Date of Examination: __/__/__

Please check one, VISIT:

Screen	Base line	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9

Weight	_____ kg	_____ lbs
Height	_____ cm	_____ ft _____ in

Blood Pressure (sitting, after _____ minutes): mmHg

Left Arm	Systolic: _ _ _	Diastolic: _ _ _
Right Arm	Systolic: _ _ _	Diastolic: _ _ _

Temperature: _ _ _ Farenheit __ __ __ Celsius

Pulse (/min): _ _ _

ECOG Performance Status (circle one): 0 1 2 3 4

NOTE: ALL X PARTS OF THE PHYSICAL EXAMINATION SHOULD BE COMPLETED BEFORE SIGNING.

Physician Name: _____, M.D.

Physician Signature: _____, M.D.

PHYSICAL EXAMINATION

Please use Physician's Notes Form, if more space is required.

	Normal	**Abnormal**	**Not Evaluated**	**If Abnormal, Describe Findings**
Appearance				
Skin				
Head				
Eyes				
Ears				
Nose				
Mouth				
Throat				
Thyroid				
Chest				
Lungs				
Breasts				

PHYSICAL EXAMINATION

Please use Physician's Notes Form, if more space is required.

	Normal	**Abnormal**	**Not Evaluated**	**If Abnormal, Describe Findings**
Heart				
Abdomen				
Musculoskeletal				
Genitalia				
Pelvic				
Rectal				
Prostate				
Vascular				
Neurological				
Lymph Nodes				
Other, specify				

PHYSICAL EXAMINATION

Please use Physician's Notes Form, if more space is required.

SPECIFIC EXAMINATION (Part 2)

EXAMPLE: HEAD AND NECK EXAMINATION FOR ORAL LEUKOPLAKIA TRIALS

	Normal	Abnormal	Not Evaluated	If Abnormal, Describe Findings
Oral Cavity				
Oropharynx				
Ears				
Neck				
Larynx				
Other				

Protocol Number (Title)
Patient ID: _____ Patient DOB: _____

LABORATORY DATA

Date of Testing: __/ __/ __ Time of Testing: __: __ am pm

Please check one, VISIT:

Screen	Base line	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9

	Parameter		Results	Units	Repeated Tests ___/___/___	Comments
HEMATOLOGY	Hemoglobin			g/dl		
	Hematocrit			%		
	RBC			Million/mm^3		
	WBC			Thous/mm^3		
	DIFFERENTIAL	Neut.		%		
		Bands		%		
		Lymp.		%		
		Mono.		%		
		Eos.		%		
		Baso.		%		
		Other				
		Other				
	Platelet Est.			mm^3		

PI:_____
Data Entry: _____
Monitor: _____

Protocol Number (Title)
Patient ID: _____ Patient DOB: _____

LABORATORY DATA

Date of Testing: __/ __/ __ Time of Testing: __: __ am pm

	Parameter	Results	Units	Repeated Tests ___/___/___	Comments
BLOOD CHEMISTRY	Total Protein		g/dl		
	Albu.		g/dl		
	Ca		mEq/l		
	P		mEq/l		
	Chol.		mg/dl		
	Uric Acid		mg/dl		
	Urea Nitro.		mg/dl		
	Creat.		mg/dl		
	Total Bili.		mg/dl		
	Alk P.		U/l		
	Na		mEq/l		
	K		mEq/l		
	Cl		mEq/l		
	CO_2				
	AST		U/l		
	ALT		U/l		
	LDH		U/l		

PI:_____
Data Entry: _____
Monitor: _____

LABORATORY DATA

Date of Testing: __/ __/ __ Time of Testing: __: __ am pm

	Parameter	Results	Units	Repeated Tests __/__/__	Comments
U	Spec. Grav.				
R	pH				
I	Albu.				
	Gluc.		mEq/l		
N	Other				
	Other				
E	Other				
	Pregnancy				
O	Spine X-Ray				
T	Chest X-Ray				
H	Agent Blood Levels[1]				
E	Other Blood Levels[1]				
R	Other				

[1] For blinded studies, to be filled in after study is completed.

STUDY DRUG ADMINISTRATION – COMPLIANCE

Date: __/ __/ __

Start Date	**Stop Date**	**No. of Doses/Pills Should Have Been Taken**	**No. of Doses/Pills Taken**	**% of Prescribed Doses/Pills Taken**

Measure of Compliance; subject is considered compliant if level of adherence is I or II for each category.

Level of Adherence	% Pills Taken	% Calendar Completed	Appointment Kept/Missed	Lab Studies Done
I	85-100	83-100	Kept All	Done within 7 Days
II	75-84	66-82	Kept within 14 Days	Done in 8-14 Days
III	65-74	25-65	Kept 15-30 Days	Done in 15-30 Days
IV	<65	<25	Kept >30 Days	Done in >30 Days
V	None	None	None	None

SCORE P___ C___ A___ L___

PI:_____
Data Entry: _____
Monitor: _____

Protocol Number (Title)
Patient ID: _____ Patient DOB: _____

CONCOMITANT MEDICATIONS

Please check one, VISIT:

Screen	Base line	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9

Provide the following information for all medications including OTCs such as aspirin, Tylenol, vitamins, laxatives, *etc.* If a medication is being used before the patient starts the study, write "PRETREATMENT" in the Start Date column. If a medication continues after off study, write "CONTINUES" in Stop Date column. **Use Physician's Notes Form for comments.**

Concomitant Meds.	**Dose and Schedule**	**Reason for Use**	**Start Date**	**Stop Date**

PI:_____
Data Entry: _____
Monitor: _____

Protocol Number (Title)
Patient ID: _____ Patient DOB: _____

DRUG CALENDAR RECORD

This form (based on 31 days/month) is given to the subject after each office visit, before the next office visit. Record the time you take the dose (*e.g.*, 8 am); if a dose is missed, do not take an extra dose on the next day. Record the day the dose was missed; *e.g.*, write down "missed" for that day. If you miss more than one dose, report it to Dr. _____ at (phone number including area code). Include specific instructions to take the medication, *e.g.*, daily with a fatty meal such as whole milk. If you develop any side effects from the medication, mark which day it occurred and report it immediately to the phone number as shown above. BRING THE BOTTLE OF MEDICATION AND YOUR DRUG CALENDAR WITH YOU EACH TIME YOU HAVE AN APPOINTMENT.

Please check one, VISIT:

Screen	Base line	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9

DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
DAY 8	DAY 9	DAY 10	DAY 11	DAY 12	DAY 13	DAY 14
DAY 15	DAY 16	DAY 17	DAY 18	DAY 29	DAY 20	DAY 21
DAY 22	DAY 23	DAY 24	DAY 25	DAY 26	DAY 27	DAY 28
DAY 29	DAY 30	DAY 31				

PI:_____
Data Entry: _____
Monitor: _____

Protocol Number (Title)
Patient ID: _____ Patient DOB: _____

ADVERSE REACTIONS

Please check one, VISIT:

Screen	Base line	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9

Use Physician's Notes Form for comments; if treatment required, indicate drug and dose.

Adverse Reactions	**Date of Onset mo/day/yr**	**No of Days ADR Observed**	**Nature of Event** **1 = Episodic** **2 = Constant/ single event** **3 = Chronic**	**Severity** **(Grades 1-4)**	**Outcome To Date** **0 = Recovered** **1 = Recovered, Residual effects** **2 = Continues** **3 = Death**	**ADR Related To Drug?** **1 = Definitely** **2 = Probably** **3 = Possibly** **4 = Not Related** **5 = Unknown**	**Outcome Treatment** **1 = Drop** **2 = Reduce dose**	**Outcome Patient** **0 = Under treatment** **1 = Alive, sequelae** **2 = Recover** **3 = Death**

PI:_____
Data Entry: _____
Monitor: _____

Protocol Number (Title)
Patient ID: _____ Patient DOB: _____

AGENT SPECIFIC ADVERSE REACTIONS, EXAMPLE: 4-HPR

Please check one, VISIT:

Screen	Base line	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9

Use the Table below to assess Agent specific ADR; use Physician's Notes Form for comments.

DERMATOLOGIC					
GRADE					
Event	**0**	**1**	**2**	**3**	**4**
Redness, rashes, inflammation	None	Mild redness or inflammation	Moderate redness or inflammation	Severe redness or inflammation	Ulceration
Dryness, itching or flaking	None	Mild dryness, itching or flaking	Moderate dryness, itching or flaking	Severe dryness, itching or flaking	Ulceration
Yellow Coloration	None	Mild	Moderate	Severe	--
Lips	Normal	Mild chapped lips	Moderate chapped lips	Severe chapped lips (bleeding)	Ulceration
Nose	Normal	Dry nose	Epistaxis (<1/day)	Epistaxis (>1/day)	Epistaxis, requires medical intervention
Hair	Normal	Mild thinning, noticeable only to subject	Moderate thinning, noticeable to others	Severe thinning	--
Other					
Other					
Other					

PI:_____
Data Entry: _____
Monitor: _____

AGENT SPECIFIC ADVERSE REACTIONS, EXAMPLE: 4-HPR

METABOLIC					
GRADE					
Event	**0**	**2**	**3**	**4**	**5**
Weight Change	Non-intentional change of 5 lbs or less	Non-intentional 6-10 lbs loss	Non-intentional 11-20 lbs	Non-intentional loss of > 20 lbs	Non-intentional loss of > 40 lbs
Other					
Other					
Other					
BEHAVIORAL					
GRADE					
Event	**0**	**2**	**3**	**4**	**5**
Headache	None	1-2/week	3-7/week	Daily, <50%/day	Daily, requires medical intervention
Emotional-anxious, nervous or irritable	No	Occasionally, <2x/week	Moderately, 3-6x/week	Significantly, daily	Extremely, requires hospitalization
Emotional	No	Occasionally, <2x/week	Moderately, 3-6x/week	Significantly, daily	Extremely, suicidal, requires hospitalization
Other					
Other					
Other					

PI:_____
Data Entry: _____
Monitor: _____

AGENT SPECIFIC ADVERSE REACTIONS, EXAMPLE: 4-HPR

SKELETAL TOXICITY					
GRADE					
Event	**0**	**I**	**II**	**III**	**IV**
Skeletal Toxicity (clinical/ X-ray findings)	Asymptomatic, no change in spine X-ray	Asymptomatic, new extraspinal tendon and ligament calcification of bone thinning on X-ray	Asymptomatic, new bone spurs developing on X-ray	Bone pain, relieved with non-narcotic pain medicines, along with development of any new bone X-ray lesion. Joint stiffness or pain relieved with non-narcotic pain medications, along with new spine X-ray findings, or any bone findings if symptoms other than spine.	Severe pain requiring narcotics for relief, along with any X-ray finding (new spine X-ray finding or any X-ray finding if symptoms other than spine)
Other					
Other					
Other					

HYPERLIPIDEMIA					
GRADE					
Event	**0**	**I**	**II**	**III**	**IV**
Plasma Cholesterol or Triglycerides (mg/dL)	<200	201-400	401-400	501-700	>700
Other					
Other					

PI:_____
Data Entry: _____
Monitor: _____

Protocol Number (Title)
Patient ID: _____ Patient DOB: _____

SOCIAL HABITS – CHANGES

Please check one, VISIT:

Screen	Base line	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9

CHANGES IN TOBACCO USE		
Date of Change mo/day/yr	**Type of Change**	**Comments**
	_____ Quit _____ Started _____ Decreased Use _____ Increased Use	
	_____ Quit _____ Started _____ Decreased Use _____ Increased Use	
CHANGES IN ALCOHOL USE		
Date of Change mo/day/yr	**Type of Change**	**Comments**
	_____ Quit _____ Started _____ Decreased Use _____ Increased Use	
	_____ Quit _____ Started _____ Decreased Use _____ Increased Use	

PI:_____
Data Entry: _____
Monitor: _____

Protocol Number (Title)
Patient ID: _____ Patient DOB: _____

EFFICACY: SEBs DATA

EXAMPLE: Aneuploidy, PCNA, TGF-ß, Micronuclei

Please check one, VISIT:

Screen	Base line	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9

Record the results in the table below; comment if necessary in the space provided below.

BIOMARKER MEASURED	RESULTS
BIOPSIES	
Aneuploidy	
PCNA	
TGF-ß	
SCRAPINGS	
Micronuclei	

Comments:

PI:_____
Data Entry: _____
Monitor: _____

Protocol Number (Title)
Patient ID: _____ Patient DOB: _____

PHYSICIAN'S NOTES

Date mo/day/yr	Type of Report 1 = ADR 2 = Medical History 3 = Follow Up	Notes

PI:_____
Data Entry: _____
Monitor: _____

Protocol Number (Title)
Patient ID: _____ Patient DOB: _____

OFF STUDY

Date Off Study: __/__/__ Date of Last Contact: __/__/__

REASON OFF STUDY	YES	NO	COMMENTS
Completed Study			
Refused Further Treatment			
Adverse Reactions			
Disease Progression			
Protocol Violation			
Other Medical Problems			
Death			
Other			

Date of Death (if patient died while on study): __/__/__

Cause of Death: _____

Autopsy Performed (circle one): YES NO

Site of Disease (if appropriate): _____

COMMENTS:

PI:_____
Data Entry: _____
Monitor: _____

Protocol Number (Title)
Patient ID: _____ Patient DOB: _____

FOLLOW–UP, EXAMPLE: 4-HPR

Fill in the box as appropriate: Date: ___/ ___/ ____

TOXICITY

Patient Experienced Clinically Significant Toxicity?	Toxicity Type	ADR Forms Completed (YES/NO)	Comments:
1 = YES[1] ~ 2 = NO [1] Complete ADR Forms	Skin Skeletal Behavioral Metabolic Hyperlipid.	_____ _____ _____ _____ _____	

DISEASE RESPONSE

Current Objective Status:	Describe 1) Overall treatment course, 2) Patient's condition while on protocol, 3) Reason for off protocol:
1 = No evidence of disease ~ 2 = Recurrent, Clinical Relapse 3 = Recurrent Biopsy 4 = New Primary, Date: ____/ ____/ _____ Appearance of New Disease: ~ 1 = NO 2 = Recurrence Site of New Disease: _____ _____	

OFF PROTOCOL TREATMENT AND FOLLOW-UP

Date Off Drug: ___/ ___/ ____	Follow-up information; 1) follow-up treatment, 2) Patient's condition, 3) cause of death, 4) other:
Reason for Stopping the Drug: 1 = ADR 5 = Violation 2 = Progression 6 = Death ~ 3 = Patient Refusal 7 = Completion 4 = Ineligible 8 = Other	
Survival Status: ~ 1 = Alive 3 = Alive, Transferred to: _____ 2 = Dead, 4 = Lost to Follow-up Autopsy (circle one): YES NO	

PI:_____
Data Entry: _____
Monitor: _____

OTHER FORMS NOT PART OF THE CRF BUT SHOULD BE PROVIDED IN PATIENT'S CHART:

1. Smoking Questionnaire
2. Dietary Questionnaire
3. Alcohol Consumption Questionnaire
4. On Study Form for the Pharmacist

OTHER FORMS AVAILABLE FOR THE STUDY:

1. NCI Chemoprevention Branch Serious Adverse Event Form